TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

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Reviewed by James E. Wilson, Jr. Date 11/06	5/85
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Type Product(s): I,(D), H, F, N, R, S	
Data Accession No(s) 259301	
Product Mgr. No. 31 (LEE)	
Product Name(s) Aqucar 542, Ucarcide 142	
Company Name (s) Union Carbide Corporation	
Submission Purpose New Application	
Chemical & Formulation Liquid	
Active Ingredient(s):	
Alkyl(50% Cl ₄ , 40% C ₁₂ , 10% C ₁₆) dimethly benzyl ammonium chloride	8.0
Glutaral de hyde	43.0

BACKGROUND

This product will be used to control microorganisms in water cooling towers and other areas requiring treatment of water.

RECOMMENDATIONS

The data submitted are adequate to place the product in the following toxicity categories:

Acute Oral - 2
Acute Dermal - 3
Skin Irritation - 1
Eye Irritation - 1

The inhalation study did not attain a level high enough to classify the product. However, an inhalation study is not required for this product.

LABELING

Revise the statement "Causes eye damage and skin irritation" to read "Cause eye and skin damage."

CRP STATUS

Product does not require special packaging.

DATA REVIEW

Reports by Bushy Run Research Center, submitted to Union Carbide Corporation, Danbury, CT 06817, dated November 26, 1984. (Accession No. 259301).

Acute Oral

- Method Five male and five female rats per group were fed a dose of 0.156, 0.312, 0.625 and 1.25 g/kg of the test via gastric gavage. An additional level of 0.078 level of was added for females only. The animals were observed for signs of toxicity and mortality 14 days. Body weights were taken on the day of dosing and weekly thereafter. All animals were subject to gross necropsy examination at time of death or after sacrifice.
- Results One male and four females died at 0.312 g/kg; one female died at 0.156 and all rats died at 0.625 and 1.25 g/kg. No females died at 0.078 g/kg. Decreased activity, hunched posture, upkempt appearance and red discharges from eyes and nose were the most

prevalent signs. Gross necropsy examinations revealed dark green to red stomachs and intestines with red liquid in animals that died. Findings is survivors were unremarkable.

Conclusion - The acute oral LD50s were calculated to be $0.320\,$ g/kg for combined sexes and $0.422\,$ and $0.243\,$ g/kg for male and female rats respectively.

Acute Inhalation

Report dated March 4, 1985.

- Method Five male and five female rats were exposed to the test material for 4 hours in a 120 liter chamber with an airflow of approximately 25 lites per minute. Atmospheric sample were taken every 30 minutes around the breathing zone of the animals. The rats were observed for 14 days after exposure and weighed weekly. Gross necropsy examination wer performed on all animals.
- Results A nomimal concentration of 22.2 ppm of glutaraldehyde was obtained. On the day of exposure closed eyes and lacrimation were the observed signs. Audible respiration was noted for 3-7 days. No mortality was reported. Gross necropsy findings were unremarkable.
- Conclusion The highest obtainable concentration of glutaraldehyde under the conditions of the study (22.2 ppm) did not produce mortality or significant clinical signs.

Acute Dermal

Method - Two groups of New Zealand white rabbits, containing 5 male and 5 female rabbits were prepared by clipping the dorsal hair. Doses of 1.0 and 2.0 g/kg were used. Male rabbits were also tested at 1.41 and 0.5 g/kg. The test substance was administered to the intact sites in one application, the sites were then occluded for 24 hours. After 24 hours the coverings were removed

from skin and the residual sample was wiped from the skin. Animals were observed for toxic signs for total of 14 days. Body weights were taken on the day of dosing and weekly thereafter. All sacrificed animals, as well as nonsurvivors were subjected to gross necropsy after the 14 day observed period.

- Results No females died. Three and four males died at 1.41 and 2.00 g/kg respectively. One male died at 0.50 g/kg. Erythema, edema and necrsosis were seen on skin. Sluggishness, unsteady gait and prostration were the signs of toxicity reported. Body weight gains were depressed in the first week. Gross necropsy findings were mottled or red lungs in three animals and gas or soft feces in the intestines of three animals. Findings in survivors were unremarkable.
- Conclusion The acute dermal LD₅₀ is greater than 2.0 g/kg for females and 1.33 ml/kg (1.46 g/kg) for males.

SKIN IRRITATION

- Method Six white rabbits received a single dermal application of 0.5 ml of the test material on one intact site.

 After application the area was covered with a gauze patch and occluded for 4 hours. The residual chemical was washed from the skin. Reactions were examined and recorded 5, 24 and 72 hours after treatment.
- Results Erythema and edema were severe through the 72 hour reading. Necrosis was seen at all sites.
- Conclusion The product is a corrosive skin irritant.

EYE IRRITATION

Method - The eyes of six New Zealand white rabbits were examined before the test. One-tenth gm of the test material instilled into the conjunctival sac of one eye of each rabbit. None of the eyes were rinsed. All eyes were examined periodically for 21 days after instillation or until irritation disappeared.

Results - One hour after instillation eyes in both groups exhibited severe iritis, corneal opacity and moderate to severe conjunctival irritation. These scores did not subside in 21 days.

Conclusion - The product is corrosive to ocular tissue.